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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,081	03/11/2004	Laurent Lecanu	1941.012US1	5330

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EXAMINER	
HAMA, JOANNE	
ART UNIT	**PAPER NUMBER**
1632	

MAIL DATE	DELIVERY MODE
08/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,081	LECANU ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *5,19,29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-18,20-28,31,32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant filed a response to the Non-Final Action of March 7, 2007 on June 7, 2007. Claims 5, 19, 29, 30 are withdrawn. Claims 1-4, 6-15 are amended. Claims 31, 32 are new.

This application contains claims 5, 19, 29, 30, drawn to an invention nonelected with traverse in the reply filed on July 20, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-4, 6-18, 20-28, 31, 32 are under consideration.

Withdrawn Rejections

35 U.S.C. 112, 1st parag., Written Description

Applicant's arguments, see page 7 of Applicant's response, filed June 7, 2007, with respect to the rejection of claims 1-4, 6-18, 20-28 have been fully considered and are persuasive. Applicant has amended the claims to indicate that the anti-oxidant inhibitor inhibits glutathione synthesis. The rejection of claims 1-4, 6-18, 20-28 has been withdrawn.

New/Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 6-18, 20-28 remain rejected and new claims 31, 32 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record, March 7, 2007.

Applicant's arguments filed June 7, 2007 have been fully considered but they are not persuasive.

Applicant indicates that the specification discloses that administration of a combination of an Abeta compound, at least one pro-oxidative compound, and at least one anti-oxidant inhibitor results in impaired performance in memory and learning tests and induces abnormal neuropathy in a brain. Thus, it is well within the skill of the art, in view of Applicant's specification, to determine whether administration of a combination of an Abeta compound, at least one pro-oxidative compound, and at least one anti-oxidant inhibitor to any non-human animal, such as a rodent. It is also well within the skill of the art to determine or detect the neuropathy induced by a particular treatment. For example, see Geula et al., 1998, of record, Gotz et al., 2004, of record, and Vaughan et al., 1981, provided by Applicant (Applicant's response, page 7). In response, this is not persuasive. With regard to Applicant indicating that it is well within the skill of the art to determine or detect neuropathy induced by a treatment, "case law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not to find out how to use it for themselves." *In re Gardner* 166 USPQ 138 (CCPA) 1970. Furthermore, the Federal Circuit has stated that:

> a specification need not disclose what is well known in the art. See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ

> 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.
> Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1005 (CAFC 1997).

The Office Action indicated there was unpredictability in arriving at Alzheimer's disease model animals (Office Action, March 7, 2007, page 9). Geula et al. 1998 teach that different species of animals provided the same treatment resulted in animals with widely differing phenotypes. Similarly, Gotz et al. teach that mice treated with Abeta42 do not exhibit any neurofibrillary tangles and indicate that the lack of tangles in mice reflects species differences between men and mice. While the claims have been amended to rodents, rodents encompass a wide variety of organisms, including mice, rats, hamsters, and guinea pigs (amongst the 4000 species of rodents encompassed by the claims, The Columbia Electronic Encyclopedia, 6th ed. [online], 2007 [retrieved on 2007-08-08]. Retrieved from the Internet:< URL: http://www.factmonster.com/ce6/sci/A0860773.html>, pages 1-3 page 1). However, given the teachings of Geula et al. and Gotz et al., an artisan cannot predict the phenotypes that result from treatment of various animals treated with Abeta protein. As such, an artisan is not enabled for "rodents."

Applicant indicates that the Examiner asserts that Geula et al. and Gotz et al. show that non-human mammalian Alzheimer's models are unpredictable. Neither Geula et al. nor Gotz et al. disclose administering a combination of agents to non-human animals to induce

neuropathology, those documents have no relevance as to the predictability of the effect of the administration of a combination of an Abeta compound, at least one pro-oxidative compound, and at least one anti-oxidant inhibitor to a non-human mammal (Applicant's response, page 8). In response, this is not persuasive. The art teaching unpredictability of one element is not indicative that a combination of three elements, which includes that one unpredictable element, is necessarily predictable. Rather, it is undue experimentation for an artisan to administer the combination of compounds to the vast number of rodents and to screen them for a neurological disease, wherein the disease is seen as hyperphosphorylated tau, amyloid plaques or neurofibrillary tangles.

Applicant indicates that Huang, et al., 1999, was cited to support the proposition that the administration of Abeta from any species does not necessarily produce any amyloid. Huang et al. speculate that this is "probably due to the three amino acid substitutions" in the rodent homolog (page 37111). Given this recognition, it is certainly within the skill of the art worker to select or screen for an appropriate Abeta to administer to a non-human animal to result in neuropathology (Applicant's response, page 8). In response, figuring out, by screening, from the vast numbers of Abeta from different species of animals, does not provide guidance in arriving at the claimed invention. As indicated above, the Federal Circuit has indicated that when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required.

The Office Action, March 7, 2007, page 10, indicated that the claims broadly encompassed any neurological disease. Claim 1 is still readable on any neurological disease,

including ALS, multiple sclerosis, and brain tumors. Applicant has not provided a response regarding this issue; thus, the claim remains rejected.

Thus, the claims remain rejected.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 indicates that the "amount" results in the rodent having hyperphophorylated tau, amyloid plaues or neurofibrillary tangles. Use of the word, "amount" is confusing because "amount" is not an active step. The claim might be amended to read, "wherein perfusing results in the rodent....", or, "wherein inducing results in the rodent...".

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Joanne Hama
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